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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,882	12/01/2000	William Lee	00786-429001 / MGH-1420.0	5708

7590

05/24/2002

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EXAMINER

FORTUNA, ANA M

ART UNIT

PAPER NUMBER

1723

8

DATE MAILED: 05/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

T.D - 8

Office Action Summary

Application No.
09/728,882

Applicant(s)
Lee et al

Examiner
Ana Fortuna

Art Unit
1723



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 20, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above, claim(s) 22-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

2. Claims 1-5, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Baurmeister et al (6,022,478)(hereinafter '478). Teaches the method of claim 1, including removing virus using a membrane having the claimed properties (abstract, column 12, last paragraph, column 18, lines 35-61, column 19, last paragraph through column 20, lines 1-38), the virus separation is disclosed in '478 (column 39-55). The polymeric side chains, including the methacrylate compound claimed in claim 3, is disclosed in '478, and the grafted chains (column 21, lines 14-35). The pore size claimed in claims 1, 2, 4 and 5 are clearly disclosed in '478 (column 12, last paragraph, and claim 12, column 37). '478 also discloses suitable membrane materials for the grafted membrane (column 19, last paragraph, and column 20, lines 1-21).

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3. (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
4. Claims 1-5, 10, 11, 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Motomura et al (5,667,684)(hereinafter '684). '684 discloses removing virus from body fluids with a membrane having the claimed properties (abstract, column 4, lines 15-54, column 5, lines 61-68, column 6, lines 62-68, column 7, lines 1-7, and column 8, lines 10-45). The membrane pore size of claims 1, 2, 4, 5 are disclosed by '684 (column 8, lines 10-21). As to claims 10-11, reference '684 discloses removing virus, e.g. HIV, at a level higher than 95 % (column 3, last paragraph, table 4, column 10, line 41). As to claim 20, bioactive virus is disclosed, e.g. HIV, as discussed above. Regarding claims 18-19, treating the membrane in solution of sodium chloride followed by rinsing with water is disclosed '684 (column 9, lines 44-68, and column 10, lines 1-10).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6, 7, 8, 9, 12, 13, 14, 15, 17, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motomura et al (5,667,684)('684). Reference '684 fails to disclose the

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limitations of the claims above. However, the concentration of claims 15, and 21 can be expected from the degree of virus removal disclosed, e.g. 99% or more. Furthermore, the same performance when the same membrane having the same porosity and attached polymeric chains on the membrane, and the same area of membrane is used under the same conditions, can be expected by one skilled in the pertinent art at the time the invention was made. As to the degree of grafting of the membrane, as claimed in claims 6-9, conditioning the membrane to provide the glycidyl, amino groups, to generate more than 2, 10 (-4) mol/g or more of sulfuric groups on the membrane surface is disclosed in reference '684 (column 3, lines 1-25). It would have been obvious to one skilled in the art to adjust the concentration of the polymeric chain compounds to generate the charge density claimed on the membrane, therefore, based on the membrane performance, the charged groups on the surface of the membrane seems to have similar concentrations. As to claim 14, the filter with low protein adsorption is disclosed (column 4, lines 31-45). Regarding claims 16-17, the sample fluid velocity is not disclosed, however, the same velocity, when the same feed composition, same membrane surface is provided when using the same membrane material under the same operating condition, should have been expected by the skilled artisan at the time the invention was made.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure, reference 4,808,315 teaches the membrane having the same pore size and material, and having the same degree of virus removal, however, the membrane is provided with the polymeric side chains claimed in the present invention. Reference WO 90/05018 teaches the membrane

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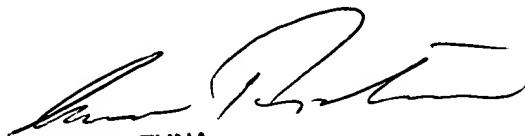
having attached groups as claimed in the present invention. References EP 0 490 940 B1, 5,981,028, and 6,258,870 B1 are also considered pertinent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana Fortuna whose telephone number is (703) 308-3857. The examiner can normally be reached on Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310 for regular responses, and (703)872-9311 for after finals.

Ana Fortuna

May 22, 2002



ANA FORTUNA
PRIMARY EXAMINER